LWG
LOWER WILLAMETTE GROUP

PORTLAND HARBOR RI/FS

INTERIM DELIVERABLE FOR HUMAN HEALTH RISK ASSESSMENT:

HUMAN HEALTH UNCERTAINTY ANALYSIS OUTLINE

DRAFT

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DO NOT QUOTE OR CITE:
This document is currently under review by US EPA and its federal, state, and tribal partners, and is subject to change in whole or in part.

Prepared for:
The Lower Willamette Group

Prepared by:
Kennedy/Jenks Consultants

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1.0 Introduction

Uncertainty is associated with every step of a risk assessment, from the sampling and analysis of concentrations of chemicals in environmental media to the assessment of exposure and toxicity. In general, the approach and methodologies used in a risk assessment are designed to err on the side of conservatism, i.e., protection of health. Uncertainty can have two components: 1) variability in data or information, and 2) lack of knowledge. An uncertainty analysis conducted as part of a risk assessment focuses on issues of variability and uncertainty associated with each of the inputs to the risk estimates.

Variability arises from true heterogeneity in exposure variables or responses, such as dose-response differences within a population or differences in contaminant levels in the environment. The values of some variables used in an assessment change with time and space, or across the population whose exposure is being estimated. Although variability can be better understood, it cannot be reduced through further study. Use of reasonable maximum exposure (RME) and central tendency (CT) scenarios provide an estimate of high-end and average exposures that may reasonably occur. The difference between the RME and CT risk estimates provides an initial evaluation of the degree of variability in exposure between individuals.

The second factor that generates uncertainty is a lack of knowledge about factors such as adverse effects or chemical concentrations. Uncertainty may be reduced by increasing knowledge about a factor through additional study. A substantial amount of uncertainty is often inherent in environmental sampling as well as in the scientific models used in risk assessment.

The Baseline Human Health Risk Assessment (HHRA) for the Portland Harbor Superfund Site (Site) will include a detailed analysis of uncertainties associated with each step of the risk assessment. The objective of the uncertainty analysis will be to understand the overall margin of conservatism in the risk estimates for consideration in risk management decisions. The uncertainty analysis will include a discussion of variability and/or uncertainty in the inputs to the risk estimates, focusing on those inputs likely to have the greatest effects on the results of the risk analyses. Where data allow, the different sources of uncertainty and variability will be assessed. Depending on the input, the uncertainty assessment may include qualitative, quantitative deterministic, or quantitative probabilistic analyses, as appropriate.

Because the HHRA has not yet been conducted, all of the uncertainties that may arise have not yet been identified and it is not known how the uncertainties may affect the risk analysis. However, based on the data collected to date and the approach of the HHRA defined in *Programmatic Work Plan, Appendix C: Human Health Risk Assessment Approach* (Integral Consulting, Inc., et al. 2004) (Appendix C of the Programmatic Work Plan), some sources of uncertainty that may affect the risk estimates in the HHRA have been identified. This interim deliverable presents a summary of the general types of uncertainty that will be included in the uncertainty

assessment and identifies uncertainties that will be further discussed in the HHRA, recognizing that some of these uncertainties may be found to have minimal impact on the risk estimates and that additional uncertainties may be identified in conducting the HHRA.

2.0 Data Evaluation

Data collected during the remedial investigation (RI), as well as data of confirmed quality that meet the data quality objectives (DQOs) for risk assessment, will be used in the HHRA to estimate risks. Sediment, surface water, groundwater seep, and biota data will be collected for use in the HHRA. Use of the U.S. Environmental Protection Agency's (EPA's) DQO planning process (EPA 2000) is anticipated to minimize the uncertainty associated with the data collected during the RI; however, a certain amount of uncertainty is inherent in environmental sampling.

Due to the iterative RI process, only beach sediment and biota data have been assessed for use in the HHRA at this time. The following data uncertainties have been identified and will be analyzed further in the HHRA to determine the potential effects on the risk estimates:

- Use of target species to represent all types of biota consumed.
- Use of whole body or fillet with skin samples to represent all fish consumption.
- Detection limits that are above analytical concentration goals (ACGs).
- Chemicals that were not included as analytes.
- Compositing methods.

Additional data collected for use in the HHRA will be assessed when available. All data uncertainties that are likely to affect the risk estimates will be analyzed in the HHRA.

3.0 Exposure Assessment

Uncertainties that arise during the exposure assessment typically have some of the greatest impacts on the risk estimates. The following subsections address uncertainties associated with exposure models, exposure factors, and exposure point concentrations (EPCs) used in the risk estimates.

3.1 MODEL APPLICABILITY

The standard exposure models used to estimate risks may result in uncertainty. The exposure models rely on identification of exposure scenarios and selection of

appropriate exposure factors for those scenarios. Uncertainty in the applicability of the exposure scenarios will result in uncertainty in the risk estimates.

3.2 EXPOSURE FACTORS

Assumptions about exposure factors typically result in a high amount of uncertainty in any risk assessment. Because many of the exposure scenarios that will be evaluated in the HHRA are highly variable and do not have standard exposure factors, uncertainties associated with the exposure factors are anticipated to have some of the greatest impacts on the risk estimates.

RME and CT values will be used for some of the exposure scenarios to evaluate the overall impact that variability in each of the exposure factors has on the risk estimates. For fish consumption, a range of ingestion rates will be used to evaluate the impact of variability on the risk estimates. In addition to the variability, there is also uncertainty associated with the exposure factors that will be used in the HHRA.

The following exposure factor uncertainties have been identified and will be analyzed further in the HHRA to determine the potential effects on the risk estimates:

- Use of soil ingestion rates for sediment exposure.
- Use of tap water ingestion rates for surface water exposure.
- Use of fish ingestion rates that are not site-specific or that are derived from limited consumption surveys.
- Use of lifetime exposure durations with variable exposure factors and environmental data.
- Assuming that all fish consumed are from the Site.
- Assumptions about a multiple-species diet.

Additional exposure factor uncertainties may be identified as the HHRA proceeds. All exposure factor uncertainties that are likely to affect the risk estimates will be analyzed in the HHRA.

3.3 EXPOSURE POINT CONCENTRATIONS

The EPC is supposed to represent the arithmetic average of the concentration of a chemical that will be contacted over the exposure duration; however, as a protective approach, an upper confidence limit on the arithmetic average is recommended for use as the EPC (EPA 1989). Given the uncertainties and variability associated with environmental data, a high amount of uncertainty is associated with calculating a

representative EPC. The following EPC uncertainties have been identified and will be analyzed further in the HHRA to determine the potential effects on the risk estimates:

- Using one-half the detection limit for non-detect results.
- Using the maximum concentration for small datasets.
- Statistical limitations of small datasets.
- Potential changes in EPCs over time.
- Possible effects of preparation and cooking methods.
- Assumptions about inorganic arsenic.
- Assumptions about chromium speciation.

Additional uncertainties may be identified as EPCs are calculated for the additional data that will be collected. All EPC uncertainties that are likely to affect the risk estimates will be analyzed in the HHRA.

4.0 Toxicity Assessment

Uncertainty factors associated with inter- and intra-species variability, extrapolations from observed adverse effect levels, and limitations in toxicological studies are incorporated into the toxicity values used in risk assessments. As a result, a high amount of uncertainty is inherent in the use of toxicity values to estimate risks. In addition to the uncertainty already included in the toxicity values, the following toxicity value uncertainties have been identified and will be analyzed further in the HHRA to determine the potential effects on the risk estimates:

- Lack of toxicity values for some chemicals.
- Use of toxicity values from surrogate chemicals for some chemicals that lack toxicity values.
- Toxicity values for polychlorinated biphenyls and applicability to environmental data.

Additional toxicity value uncertainties may be identified as the HHRA proceeds. All toxicity value uncertainties that are likely to affect the risk estimates will be analyzed in the HHRA.

5.0 Summary

This interim deliverable presents an overview of the uncertainties that are likely to be analyzed in the HHRA. As additional data are collected and the HHRA proceeds, the

uncertainties identified in this interim deliverable may be eliminated by addressing data gaps or may be found to have minimal impact on the risk estimates. Furthermore, additional uncertainties may be identified. The HHRA will include an analysis of uncertainties remaining at the time of the HHRA and will focus on those uncertainties that are likely to have the greatest impact on the risk estimates.

6.0 References

EPA. 1989. Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A), Interim Final. Office of Solid Waste and Emergency Response, EPA/540/1-89/002. December 1989.

EPA. 2000. Guidance for the Data Quality Objectives Process, EPA QA/G-4. EPA/600/R-96/055. U.S. Environmental Protection Agency, Office of Environmental Information, Washington DC.

Integral Consulting, Inc., Windward Environmental, LLC, Kennedy/Jenks Consultants, Anchor Environmental, LLC, Groundwater Solutions, Inc. 2004. Portland Harbor RI/FS Programmatic Work Plan. Prepared for The Lower Willamette Group. Integral Consulting, Inc., Mercer Island, WA; Windward Environmental, LLC, Seattle, WA; Kennedy/Jenks Consultants, Portland, OR; Anchor Environmental, LLC, Seattle, WA; Groundwater Solutions, Inc., Portland, OR.